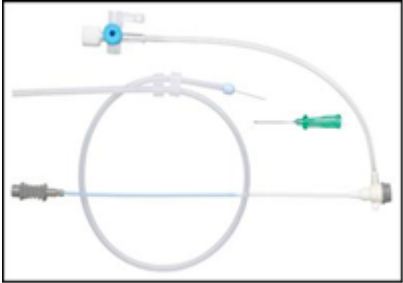


# Medical Device Alert

Ref: MDA/2013/083 Issued: 13 December 2013 at 15:00

Device	
<p>TransRadial artery access kit.</p> <p>Manufactured by Arrow International (a division of Teleflex Medical).</p> <p>Specific part numbers and lot numbers.</p>	

Problem	Action
<p>Risk of delay to patient treatment.</p> <p>Arrow International are recalling certain models and lot numbers of their TransRadial artery access kits because the introducer needles packaged within the kits can be partially or fully occluded.</p> <p>Arrow International issued a <a href="#">Field Safety Notice (FSN)</a> dated 09 October 2013. The FSN lists the part and lot numbers that are affected.</p> <p>The manufacturer has not received sufficient confirmation that this FSN had been received and acted upon.</p>	<p>Identify and quarantine affected kits pending return to Teleflex Medical.</p> <p>Ensure that all users are aware of the advice given in the Arrow International <a href="#">FSN</a> for identifying and returning affected stock.</p> <p>Fill in the acknowledgement form in the FSN and return it to Teleflex Medical.</p> <p><b>Action by:</b> All medical, nursing and technical staff involved in the use of these devices. Staff involved in the purchase of these devices.</p>
CAS deadlines	Contact
<p>Action underway: 23 December 2013</p> <p>Action complete: 17 January 2014</p> <p><b>Note: These deadlines are for systems to be in place to take actions.</b></p>	<p>Teleflex Medical Hélène Sauvage Tel: 01494 532 761 Email: <a href="mailto:orders.uk@teleflex.com">orders.uk@teleflex.com</a></p>

## Distribution

This MDA has been sent to:

- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.

Below is a suggested list of recipients.

### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All departments
- All staff
- All wards
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Medical directors
- Paediatric intensive care units
- Paediatric medicine, directors of
- Purchasing managers
- Risk managers
- Supplies managers

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

Teleflex Medical  
Hélène Sauvage

Tel: 01494 532 761

Email: [orders.uk@teleflex.com](mailto:orders.uk@teleflex.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/083** or 2013/010/010/081/013.

### Technical aspects

Louise Mulroy and Patrick Sweeney  
Medicines & Healthcare Products Regulatory Agency  
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ  
Tel: 020 3080 7344 or 020 3080 6898 Fax: 020 8754 3965  
Email: [louise.mulroy@mhra.gsi.gov.uk](mailto:louise.mulroy@mhra.gsi.gov.uk)  
[patrick.sweeney@mhra.gsi.gov.uk](mailto:patrick.sweeney@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge  
Medicines & Healthcare Products Regulatory Agency  
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ  
Tel: 020 3080 7128 Fax: 020 8754 3965  
Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@mhra.gsi.gov.uk)

### How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>  
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group, Room 17, Annex 6, Castle Buildings, Stormont Estate,  
Dundonald BT4 3SQ  
Tel: 02890 523 704 Fax: 02890 523 900 Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>  
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre  
NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB  
Tel: 0131 275 7575 Fax: 0131 314 0722 Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)  
<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 5801 Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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